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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,043	02/17/2004	Elizabeth Bates	SF0977XB	1489

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,043	BATES ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 10-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures, except for the following:

It does not appear that all of the sequences disclosed in the specification as filed are provided with the appropriate SEQ ID NOS. in compliance with the Sequence rules as set forth in 37 CFR 1.821(d).

For example, the sequences disclosure on page 10 of the instant specification does not appear to have SEQ ID NOs.

Applicant is required to review the entire instant application for compliance with the Sequence Rules.

2. Applicant's election of Group III, filed 11/18/2005, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-16 are pending.

Claims 1-6, 10-16 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions.

Claims 7-9, drawn to a binding compound specifically binds to the polypeptide with SEQ ID NOs: 2, 4, 6, 8, or 10, are under consideration.

3. Applicant's claim for domestic priority under 35 U.S.C. 120, 121 and 365(c) is acknowledged. However, the subject matter claimed in the instant application only has support under 35 U.S.C. 112 in priority applications 09/869,388 and PCT/US99/30004. Specifically, insufficient support was identified for the limitation of "SEQ ID NOs: 6, 8, and 10" in USSNs 09/223,919 and 09/224,604. Consequently, the claims have been accorded the priority of the applications 09/869,388 and PCT/US99/30004, which is 10/09/2001 and 12/29/1999, respectively.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120 and 365(c), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

The specification on page 1, line one should be amended to reflect the status of the priority applications 09/869,388, which is now patented, PCT/US99/30004, and 09/233,919, and 09/224,604, which are both abandoned.

4. Applicant's IDS, filed 02/17/2004, is acknowledged and considered.

5. The application is required to be reviewed and all spelling, TRADEMARK, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent application, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

6. For Examination purposes, an isolated polypeptide reads as "comprising **the** amino acid sequence derived from SEQ ID NO:2, 4, 6, 8, 0r 10". Applicant is notified that "an isolated polypeptide comprising **an** amino acid sequence derived from SEQ ID NO:2, 4, 6, 8, 0r 10" encompasses amino acid sequence comprise the full-length of SEQ ID NOs 2, 4, 6, 8, or 10 or any portion of the SEQ ID NOs 2, 4, 6, 8, or 10. The claim is anticipated by any amino acid sequences with two or more residues. Amending the claims to recite "**the** amino acid sequence" would read on the entire SEQ ID NO.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-9 are indefinite in that they depend on non-elected claims. Applicant should amend the claims as independent from non-elected claims.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies, does not reasonably provide enablement for any binding compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification provides insufficient enabling description of the claimed "binding compound". A person skill in the art is not enabled to make and use any "binding compound" which specifically binds the polypeptide comprising an amino acid sequence derived from SEQ ID NOs:2, 4, 6, 8, or 10 as encompassed by the full breadth of the claims as currently recited. The specification only discloses antibodies (see pages 2 and 18-21 of the specification as-filed).

The term "binding compound" encompasses any compound that binds to poly polypeptides derived from SEQ ID NOs:2, 4, 6, 8, or 10. The structure of such compound cannot be readily predicted by one skilled in the art based upon the guidance provided in the specification. Therefore, applicant does not appear to provide sufficiently enabling disclosure regarding how to make and use any "binding compound" other than antibodies. Reasonable correlation must exist between the scope of the claims and the scope of the enablement set forth.

While "binding compound" may have some notion of the function of the claimed product, there is insufficient biochemical or structural information to enable the skilled artisan to make and use the "binding compound" as broadly claimed.

In view of the lack of guidance and working examples, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Adema et al. (WO 98/24906, cited in IDS filed 02/17/04) (see entire document) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886).

Adema et al. teach an isolated polypeptide FDF03 from mammalian monocyte comprising the amino acid sequence of SEQ ID NO:2 that is 100% identical to claimed SEQ ID NO:2. Adema et al. further teach that binding composition such as monoclonal antibody or antibody fragment that binds with specificity to the said polypeptide or peptide exhibiting at least about 85% sequence identity can be made using the polypeptide as antigen (see entire document, particularly pages 7, 22-27, 33-38 and claims 1, 8 and 9).

It is noted that SEQ ID NOs 2, 4, 6, 8, and 10 share substantial sequence homology (see pages 6-10 of the specification as-filed for sequence alignment).

As evidenced by Bost et al, antibodies can be specific and cross-react with the antigen. For example, antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., "Results, page 579).

As further evidenced by Bendayan, the specific reactivity of a monoclonal antibody can be highly specific yet cross-react with antigens from different species or even distinct proteins not related to the original antigen (page 886, last paragraph).

Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific. Therefore, the reference antibody to SEQ ID NO:2 is specific to proteins with SEQ ID NO: 4, 6, 8, and 10.

Therefore, the reference teachings anticipate the claimed invention.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
January 19, 2006

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